K122357

510(k) SUMMARY

Merits Health Products Co., LTD.
510(k) Premarket Notification

JAN 9 2013

Submitter:

Merits Health Products Co., LTD.
No.18, Jingke Rd., Nantun Dist.
Taichung City 40852, Taiwan (R.O.C.)

Contact Person:

Vincent Chen
Merits Health Products Co., LTD.
No.18, Jingke Rd., Nantun Dist.,
Taichung City 40852, Taiwan (R.O.C.)
Phone: +886-4-23594985 ext.200
Fax: +886-4-23503962

Date Prepared:

July 30, 2012

Proprietary Name:

Merits Model P322 Powered Wheelchair

Common name:

Powered Wheelchair

Classification name:

Powered Wheelchair

Comparison to Predicate Devices:

This submission indicates the Substantial Equivalence of Merits Model P322 FWD Powered Wheelchair with the predicate Hoveround Teknique FWD mk4 Power Chair (K090108). P322 has the same intended uses and similar indications, technological characteristics and principles of operation with predicate device.

Device Description

Model P322 Powered Wheelchair is battery powered, front wheel motor driven and is controlled by the PG power wheelchair VR-2 50amp controller. The user interface is a joystick. P322 is powered by two 12 VDC 34ah (U1) batteries. The batteries are charged by 4A off-board charger connect with 3-pin Microphone Connector to charging socket on joystick. The approximate driving range on fully charged batteries is up to 28km (18mi). The chair frame is a rived nut and welded steel construction and includes two front drive wheels with drive units (including motor, gear, brake), batteries and rear pivoting casters. Depending on users needs, the joystick motor control is mounted to the left or right armrest. When the user activates the joystick, the controller receives a signal to release the brakes. With the brakes released, the wheelchair is allowed to move in the direction the joystick is actuated. When the user releases the joystick, the chair slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user stop by letting go of the joystick.

The upholstery of the device complies with EN 1021-1/-2:2006: Furniture: Assessment of the ignitability of upholstered furniture: Ignition source: Smouldering cigarette/ Match flame equivalent

The device can be operated on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

The Merits Model P322 is substantially equivalent to Hoveround Teknique FWD mk4 Power Chair (K090108). Both products are battery power, motorized designed for use with powered wheelchairs. Performance characteristics and drive mechanisms are similar and all have the same intended function and use which is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair. Additional, they are all constructed from the same basic materials, have the same basic operational principles and all use DC batteries as their source of power.

Although there are some minor differences between P322 and its predicate device. But they raise no new issues of safety or effectiveness. Performance data demonstrate that P322 is safe. The non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do no raise any new questions of safety or effectiveness.

Intended Use

The Merits Model P322 Powered Wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

Discussion of Non-clinical Tests Performed for Determinations of Substantial equivalence are as follows:

ISO 7176-1:1999	Determination of Static Stability
ISO 7176-2:2001	Determination of Dynamic Stability of electric wheelchairs
ISO 7176-3:2003	Determination of effectiveness of brakes
ISO 7176-4:2008	Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
ISO 7176-5:2008	Determination of overall dimensions, mass and maneuvering space
ISO 7176-6:2001	Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-7:1998	Method of Measurement of Seating and Wheel Dimensions
ISO 7176-8:1998	Requirements and test methods for static, impact and fatigue strengths
ISO 7176-9:2009	Climatic tests for wheelchairs
ISO 7176-10:2008	Determination of obstacle-climbing ability of electrically power wheelchairs
ISO 7176-11:1992	Test dummies
ISO 7176-13:1989	Determination of coefficient of friction of test surfaces
ISO 7176-14:2008	Power and control systems for electrically powered wheelchairs and scooter- Requirements and test methods.
ISO 7176-15:1996	Requirements for Information Disclosure, Documentation and Labeling
IEC 60601-1:1988	Medical electrical equipment Part 1: General requirements for safety
IEC 60601-1-2:2007	Electromagnetic Compatibility - Requirements and Tests
ISO 14971:2007	Medical devices -- Application of risk management to medical devices
EN 1021-1:2006	Furniture Assessment of the ignitability of upholstered furniture : Ignition source: Smouldering cigarette
EN 1021-2:2006	Furniture Assessment of the ignitability of upholstered furniture : Ignition source: Match flame equivalent

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

Conclusions

According to comparison table, the differences on weight capacity, function of elevate, recline and dimension of width do not deleteriously affect the safety and effectiveness of the device.

So based on the design, performance specifications and testing and intended use, the Merits Model P322 Powered Wheelchair is substantially equivalent to Hoveround Teknique FWD mk4 Power Chair (K090108).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Merits Health Products CO., LTD
Mr. Vincent Chen
No. 18 Jingke Road
Nantun Dist
Taichung
China (Taiwan) 40852

JAN 9 2013

Re: 510(k) Number: K122357
Trade/Device Name: Merits Model P322 Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr.Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) File Number:

Device Name: Merits Model P322 Powered Wheelchair

Indications for Use: The Merits Model P322 Powered Wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Neurological and
Physical Medicine Devices
510(k) Number: K122357